EXHIBIT A

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UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC **PLAINTIFFS' SUBMISSION OF CASES FOR BELLWETHER GROUP 1**

In accordance with Case Management Orders Nos. 11, 18, and 20, Plaintiffs provide this memorandum regarding their proposed cases for inclusion in Bellwether Group 1. Both sides have agreed on the inclusion of the case of Deborah Mulkey, case no. 16-CV-00853, in Bellwether Group 1. Ms. Mulkey's case involves an Eclipse filter that has perforated and become embedded in her inferior vena cava ("IVC").

In addition to Ms. Mulkey's case, Plaintiffs propose the Court select the following five cases to complete Bellwether Group 1:

- Debra Tinlin, case no. 16-CV-00263 (Recovery filter);
- Sherr Unna Booker, case no. 16-CV-00474 (G2 filter);
- Brent Dewitt, case no. 16-CV-00474 (G2 filter);
- Joseph Mixson, case no. 16-CV-00268 (G2 filter); and
- Justin Peterson, case no. 16-CV-00774 (Eclipse filter)[1]

[1] As discussed below, Plaintiffs offered to stipulate to the inclusion of Lisa Hyde, case no. 16-CV-00893 (G2 filter), in Bellwether Group 1 on the condition that they be permitted to

Collectively, with the Mulkey case, these cases represent the devices and range of failure modes that are at issue in this MDL[2] and will provide the parties the opportunity to present their best arguments and to test their theories and defenses at trial.

I. The Selection of Bellwether Trial Cases

> The term bellwether is derived from the ancient practice of belling a wether (a male sheep) selected to lead his flock. The ultimate success of the wether selected to wear the bell was determined by whether the flock had confidence that the wether would not lead them astray, and so it is in the mass tort context. The notion that the trial of some members of a large group of claimants may provide a basis for enhancing prospects of settlement or for resolving common issues or claims is a sound one that has achieved general acceptance by both bench and bar.

In re Chevron U.S.A., Inc., 109 F.3d 1016, 1019 (5th Cir. 1997).

As noted by United States District Court Judge Eldon Fallon in his article *Bellwether Trials in Multidistrict Litigation*, the "ultimate purpose of holding bellwether trials … was not to resolve the thousands of related cases pending in either MDL in one 'representative' proceeding, but instead to provide meaningful information and experience to everyone involved in the litigations." Fallon, Grabill, Wynne, *Bellwether Trials in Multidistrict Litigation*, 82 Tulane L. Rev. 2323, 2332 (2008) (referencing the use of bellwether trials in the Propulsid and Vioxx MDLs); *see also In re Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, No. MDL 05-1708, 2006 WL 409200, at *1 (D. Minn. Jan. 31, 2006) (bellwethers are to "illustrate and inform the parties and the Court of important issues in the litigation").

"A bellwether trial also allows a court and jury to give the major arguments of both parties due consideration without facing the daunting prospect of resolving every issue in every action. ... [E]very experienced litigator understands that there are often a handful of crucial issues on which the litigation primarily turns. A bellwether trial allows each party to present its best arguments on these issues for resolution by a trier of fact." *In re Methyl Tertiary Butyl Ether Prod. Liab. Ligit.*, 2007 WL 1791258 *2 (S.D.N.Y. June 15, 2007).

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take trial deposition of Ms. Hyde's treating doctors. In that case, Plaintiffs would substitute the Hyde case for the Peterson case above.

[2] There are no Meridian or Denali cases in Discovery Group 1. Hence, Bellwether Group 1 will necessarily focus on the first three devices – Recovery, G2, and Eclipse.

Indeed, Judge Fallon similarly noted that "bellwether trials can be effectively employed for nonbinding informational purposes and for testing various theories and defenses in a trial setting." Fallon, *supra*, at 2337. This is echoed in the Manual for Complex Litigation, which urges the use of bellwether trials to assess the relative nature and strength of claims and to provide information to aid in global settlement discussions. Manual for Complex Litigation § 22.315 (Fourth ed. 2005). Further, the Manual for Complex Litigation acknowledges that "verdicts in representative cases inform the parties as to the likely range of verdicts in similar cases." *Id.* § 22.93.

II. Bard's IVC Filters, Sales Numbers, and Their Signature Failure Modes

For the three devices that will be at issue in Bellwether Group 1, the following background for the relevant devices as well as their associated failure modes are relevant to determination of the appropriate composition of that group.

A. Recovery (32,000 Sold) – Migration, Perforation, and Fracture

Bard began limited sales of the Recovery IVC filter as a permanent device in December 2002; it began sale of the device with full market release for retrievable indication on January 1, 2004. Between January 1, 2004 and September 2005 (when it took Recovery off the market), Bard sold more than 32,000 Recovery filters.

By December 7 of 2004, there were seven patient deaths associated with migrations of Recovery filters to patients' hearts. By December 17, 2014, there were 67 reports of "potentially serious hazards" related to the Recovery filter, ten of which were associated with patient death. *See* Ex. 1. Bard's analysis of the Recovery's adverse event rates at that time revealed:

> Reports of death, filter migration (movement), IVC perforation, and filter fracture associated with Recovery were seen in the MAUDE database at reporting rates that were 4.6, 4.4, 4.1, and 5.3 higher, respectively, than reporting rates for all other filters. These differences were all statistically significant.

Id. (emphasis added).

Similarly, the medical literature and studies have shown that these failure modes – migration, perforation, and fracture – are prevalent for the Recovery filter. Across

multiple studies, the Recovery has been found to migrate at rates of up to ten percent; it has been found to perforate the IVC between 27 and 100 percent of the time; and it has been found to fracture between 5.5 and 25 percent of the time with projections of nearly 40 percent fracture after five years of indwell time.[3] In 2009, Hull, et al, published the results of a retrospective evaluation of 14 patients who received the Recovery filter. At long term follow-up (mean 899 days), all 14 patients had filter arm perforations; 36 percent had leg perforations; and 21 percent had fractures associated with migration. The authors concluded that Recovery filter limb perforation increases over time and is associated with a 21 percent incidence of filter arm fracture and migration. The authors recommended follow up imaging for patients receiving these filters.[4]

B. G2, G2 Express, G2x (154,000 Sold) – Caudal Migrations, Perforations, and Fractures

Between September 2005 and the end of 2011, Bard sold more than 154,000 G2, G2 Express, and G2x filters. Bard initially obtained clearance for the G2 as a permanent device and began selling it on September 7, 2005. It obtained clearance of the G2 as a retrievable device on January 15, 2008 and began marketing it for retrievable indication at that time. In the G2 IVC filter, Bard redesigned certain elements of the Recovery filter in an attempt to address some of the complications caused by the Recovery filter. Nonetheless, in seeking and obtaining 510(k) clearance for the G2, Bard identified the Recovery as its predicate device, and the G2 retained many of its design features and resulting complications.

For example, by changing the width of the base of the device and strengthening its hooks, Bard sought to reduce the rate of filter migration toward the heart (cranial

[3] These statistics from various studies are compiled in the recent meta-study analysis by Doctors Steven Deso, Ibrahim Idakoji, and William Kuo published in Seminars in Interventional Radiology in 2016: Deso, Idakoji, & Kuo, Evidence-Based Evaluation of Inferior Vena Cava Filter Complications Based on Filter Type, Semin. Intervent. Radiol. 2016; 33:93-100, a copy of which is attached as Ex. 2.

[4] Hull JE, Robertson SW. Bard Recovery Filter: Evaluation and Management of Vena Cava Limb Perforation, Fracture, and Migration, J Vasc Interv Radiol 2009; 20:52-60.

migration). However, the result of that modification was only to change the direction in which the filter migrated – the G2 migrated just as much, if not more, than the Recovery, except it moved in the other direction (caudally). By early 2006, Bard recognized this problem in an internal Health Hazard Evaluation (HHE) addressing migrations of G2 filters – the vast majority of which were "caudal" migrations. *See* Ex. 3. Bard found the severity of the hazard to be "Critical" (*id.*) and its internal analysis was that the risk of the filter was unacceptable. *See* Ex. 4.

Bard also conducted a retrievability study for the G2 filter called the Everest study. Everest's purpose was not to measure the G2's safety or efficacy, but rather to determine its retrievability after periods of indwell. Nonetheless, the study tracked complications and found that the G2 migrated caudally in 12 percent of the cases;[5] it further found perforations in 26 percent of the cases; and, despite an average indwell time of only 140 days, there was a fracture among the approximately 80 patients.[6]

Additionally, because of the high fracture rate for the Recovery filter, Bard tracked monthly and cumulative reported fractures in monthly filter fracture analysis reports for all of its filters. Those internal reports showed clearly that not only did the number of fractures increase over time but the rate of fracture increased over time for all Bard filters.

Bard's internal reports were consistent with the medical literature which reports migration rates between 12 percent (52 percent when measuring at 5 millimeters) and 25

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[5] This rate was based on measured movement greater than 20 millimeters; the FDA Guidance document for IVC filters suggests measuring movement greater than 5 millimeters as migration. Using the FDA standard for measuring migration, the migration rate in the Everest study was greater than 50 percent.

[6] Studies (and Bard's own internal analysis) suggest strongly that fracture rates increase over time and particularly after the first 180 days. *See, e.g.*, Lynch, MD & Kekulawela, MD, Removal of the G2 Filter: Differences between Implantation Times Greater and Less than 180 Days, J. Vasc. Interv. Radiol. 2009; 20:1200-1209; *see also* Nicholson W, Nicholson J, Toerico P, et al. Prevalence of Fracture and Fragment Embolization of Bard Retrievable Vena Cava Filters and Clinical Implications Including Cardiac Perforation And Tamponade, Arch Intern Med 2010 170:1827-31 (reporting 25% fracture rate for Recovery and 12% fracture rate for G2, but extrapolating that, at 50 months, "the prevalence for fracture rate [of the G2] would be identical to that of the Bard Recovery filter").

percent for the G2 filters (including G2, G2 Express, G2x, Eclipse, and Meridian). Similarly, studies have shown that the G2 devices fracture at rates between 3.4 and 12 percent with an expected fracture rate of 38 percent at five years.[7] They also perforate the IVC at rates between 18 and 44 percent. Those same studies show these devices tilt more than 15 degrees between 11.5 and 18 percent of the time.

Moreover, as Bard knows, these complications are related. For example, the occurrence of migration or tilt is likely to lead to further complications, including perforation or fracture. *See* Ex. 5; Ex. 6.

C. Eclipse (66,000 Sold) – Continued Caudal Migrations, Perforations, and Fractures

Bard introduced the Eclipse IVC filter on January 1, 2010. Between January 1, 2010 and the end of 2014, Bard sold over 66,000 Eclipse filters. In its 510(k) clearance application materials, Bard identified the G2 Express as the predicate device for the Eclipse. Despite the name change, the Eclipse was essentially the G2x with electropolishing of the arms and legs. "The primary modification from the predicate device, the G2 Express Filter System…was an improvement of the surface finish of the filter raw material wire by electropolishing the wire prior to forming the filter. A cosmetic colorant modification to some of the molded components of the delivery kits was also made."

[7] In 2012, Vijay et al. published a study comparing the Recovery and G2 filters. Among 548 patients presenting for filter retrieval, 63 had fractured filters (12%). The distal embolization rate of fractured filter components was 13 percent. They also found that filter fracture rates increase with longer dwell times. Fracture of filter affected successful removal of the filter components (98.4% vs. 53.4%). Vijay K, Hughers JA, Burdette AS, et al., Fractured Bard Recovery, G2, and G2 Express Inferior Vena Cava Filters: Incidence, Clinical Consequences, and Outcomes of Removal Attempts, J Vasc Interv Radiol 2012; 23:188-94. In 2014, Dr. An published a retrospective study examining 684 patients with G2 devices; 13 patients were identified with fractures. Struts were identified in the pulmonary artery, right ventricle, pericardium, iliac vein, and kidney. They estimated a 5-year fracture prevalence of 38%. An T, Moon E, Bullen J, et al., Prevalence and Clinical Consequences of Fracture and Fragment Migration of the Bard G2 Filter: Imaging and Clinical Follow-Up in 684 Implantations, J. Vasc. Intervent. Rad. 2014; 25(6):941-948.

Bard was aware that the G2 design filter required safety design changes to deal with not just fractures, but migrations, tilting, and perforations. Nonetheless, the Eclipse "was the same as G2X in every way but one." Since the Eclipse was not designed to deal with the equally serious complications and design deficiencies of migration, tilt, and perforations that plagued the G2 for five years prior, it too should not have been released by Bard as a new, improved, safer and more effective IVC filter.

However, as Bard's then Vice President of Research & Development testified, there is no evidence in Bard's testing that the electropolishing improved fracture resistance, migration resistance, or corrosion resistance. *See* deposition transcript A. Raji-Kubba, Ex. 7, at 167:23-168:8. Rather, as Bard's internal documents state, electro-polishing the device was to give it a surface finish "consistent with emerging industry standards." According to other internal memoranda, the purpose of the name change was to "create break with the baggage associated with the previous versions despite the fact that the new iteration was the same as G2X in every way but one." *See* Ex. 5.

That same internal Bard memorandum, approximately 3 months after launch of the Eclipse, references a future "Eclipse Anchor Filter" that would be designed to improve "caudal migration resistance," and "reduce subsequent tilt, fracture and penetration." The Eclipse, however, did not address any of these.

Thus, over time, its failure rates are essentially those of the G2 devices; and, the medical literature, including a recent meta-analysis by Doctors Deso, Idakoji, and Kuo (Ex. 2), has essentially treated them as such.

III. MDL Case Filing Statistics

There are presently in excess of 1,700 cases filed in this MDL. From those, Plaintiffs have received and reviewed completed Plaintiff Profile Forms (PPFs) for 954 cases. Based on those forms, the devices at issue in those cases break down as follows:

Device	Number of Cases	MDL percentage
SNF	10	1%
Recovery	100	10.5%
G2 models	394	41.3%

(G2, G2 Express, G2x)		
Eclipse	209	21.9%
Meridian	120	12.6%
Denali	110	11.5%
Unknown	11	1.1%

These numbers are slightly different than one would expect from Bard's sales numbers for IVC filters. Given that the complication rates of the Recovery, G2 (including the G2 Express and G2x), and the Eclipse are relatively similar – particularly over time – one would expect case composition to be roughly equal to their relative sales rates. Eclipse, however, appears to be overrepresented based on Bard's sales numbers.

Device	**Units Sold**	**Relative Rate**
Recovery	32,000	12.7%
G2	154,000	61.1%
Eclipse	66,000	26.3%

Thus, relative to the G2 devices, Eclipse complaints appear in the first 954 PPFs at a rate higher than expected. The latter numbers suggest a ratio of approximately 1.88:1 whereas sales and complications would suggest a ratio closer to 2.33:1. There does not appear to be significant reason for there to be the overrepresentation of Eclipse cases at this point. Thus, Plaintiffs expect that the rate of Eclipse filings will regress to the expected rate as more cases are filed and all PPFs are submitted.

Based on the completed PPFs, the reported failure mode frequency of cases in the MDL is as follows:

Failure Mode	**Cases Reporting**	**Frequency**[8]
Fracture	249	26.1%
Perforation of filter strut(s) into organs	325	34.1%
Migration of entire filter to the heart	128	13.4%
Tilt with filter embedded in IVC wall	317	33.2%
Irretrievable	404	42.3%
Embedment	306	32.1%

Those numbers are relatively consistent with the rates reported in the medical literature for these devices. That being said, the PPFs do not capture certain kinds of complications – migrations not to the heart; migrations of fractured pieces; perforations not into organs. Moreover, the PPFs and failure mode categories do not capture the nature

[8] Plaintiffs have the ability to report multiple failure modes on their profile forms.

and extent of the injury and damages caused, the potential for future injury. And, many plaintiffs may not actually have had a doctor fully review the status of their filters and, thus, may not be accurately reporting their problems. It is also the case that those plaintiffs who have not yet had their filter removed are at increasing risk to suffer failures and injuries in addition to those reported to date. Thus, Plaintiffs submit that the published medical literature reporting, based on qualified and dedicated studies, is more accurate as to the incidence and distribution of failures of these devices.

Nonetheless, even these MDL statistics demonstrate that the majority of cases involve multiple failure modes.

IV. MAUDE Reporting of Bard IVC Filters

A review of the MAUDE (FDA) public reporting database for complaints relating to IVC filters through February 2016 reveals that Bard's IVC filters are responsible for 35 percent of the total reported complications (2,276 out of 6,510 reports). Relevant to the selection of Bellwether Group 1 cases, of the IVC filter complaints for Bard devices, 21 percent (470) are for Recovery filters; 51 percent (1,171) are for G2/G2 Express/G2x; and ten percent are for Eclipse filters (223).

V. Plaintiffs' Proposed Cases

Plaintiffs propose a mix of cases that will be representative of the filters and the range of failure modes at issue with these devices and in the MDL. Plaintiffs' proposed cases further provide the parties the opportunity to present their best arguments and to test their theories and defenses at trial.

The following chart summarizes those cases and Plaintiffs provide a more detailed explanation of each case below:

Name	Device	Retrieval attempt(s)	Failure Mode(s)	Residual(s)
Tinlin	Recovery	Unsuccessful retrieval attempt; subsequent open surgery to remove strut in heart	Fracture of 2 struts, Perforation of IVC and spine.	Filter body and strut pieces in lung

Booker	G2	Percutaneous retrieval of filter body & 1 strut; subsequent open retrieval of strut in right ventricle	Caudal migration, Fracture of 3 struts, Strut perforation of aorta, Tilt and embedment in IVC wall.	Strut embedded in IVC
DeWitt	G2	Two unsuccessful retrieval attempts; subsequent percutaneous retrieval of strut in lung	Fracture of 2 struts, Migration of strut, Tilt and embedment, Perforation of IVC.	Filter embedded in IVC
Mixson	G2	Unsuccessful retrieval attempt	Caudal Migration (Filter), Tilt, Perforation of IVC and duodenum, Embedded.	Filter embedded in IVC
Peterson	Eclipse	Open abdominal surgery to remove filter	Perforation of IVC, duodenum, and psoas muscle.	None
Mulkey	Eclipse	Unsuccessful retrieval attempt	Perforation of IVC, Tilt.	Filter in IVC

A. Deborah Tinlin - Recovery

Debra Tinlin is 52 years old and resides in Wisconsin. She has been married for over 25 years to police detective James Tinlin, and the Tinlins have an adult son. Ms. Tinlin served in the U.S. Army from 1982 to 1985. She was also employed as a preschool teacher. In 2004, Ms. Tinlin was diagnosed with multiple scleroses with complete paralysis of the right lower extremity. She uses a power wheelchair for mobility. Ms. Tinlin has other medical conditions which include depression, GERD, reactive airway disease, Sjogren's syndrome (an immune system disorder), diabetes, arthritis, and morbid obesity. Her surgical history includes colon surgery, hemorrhoidectomy, hysterectomy, dilation and curettage procedure, thyroidectomy, cataract, and back surgery.

In 2005, Ms. Tinlin was hospitalized for exacerbation of multiple sclerosis. She developed deep vein thrombosis (DVT) and bilateral pulmonary embolisms (PE) during the hospitalization. On May 7, 2005, she underwent an implant of a Recovery filter which was performed by Joshua Riebe, M.D. at St. Mary's Hospital in Wisconsin.

In 2013, two fractured filter struts migrated to Ms. Tinlin's right ventricle, causing massive pericardial effusion, cardiac tamponade, cardiogenic shock, and multi-organ

failure. She underwent emergency intubation at Aurora BayCare Medical Center and Alexander Roitstein, M.D. performed emergent surgical drainage of the pericardial effusion. On July 31, 2013, David Kress, M.D. successfully removed one of the fractured struts through an open heart surgery, but the second strut could not be located in the heart and was later identified in the basilar interventricular septum. The filter body remains in Ms. Tinlin's body, with several struts projecting outside the lumen of the vena cava and adjacent to the lumbar spine, along with several pieces of wire in her lungs, which doctors believe to be fragments of the second fractured strut.

Plaintiffs believe that Ms. Tinlin would be an appropriate bellwether case because she received a Recovery filter that had signature failure modes for that device: cranial migration and fracture. As the sole Recovery case in the parties' recommendations from Discovery Group 1, her case is the sole representative of the hundreds of Recovery cases in this MDL. Indeed, as reported to MAUDE, more than 20 percent of all complaints regarding Bard filters related to the Recovery filter. Accordingly, it is important to have a Recovery filter in the bellwether trials. Moreover, the two complications Ms. Tinlin experienced are precisely the issues that Bard had with the Recovery shortly after its full market release when it began experiencing a tremendous increase in adverse events – particularly migrations and fractures.

B. Sherr Una Booker – G2

Sherr Una Booker is a 46 year old mother of two who works at Home Depot and resides in Atlanta, Georgia. In June 2007, Ms. Booker was admitted to New York Methodist Hospital in Brooklyn, New York for symptoms related to cervical cancer. Due to a history of PEs while on anticoagulants and planned surgery, a Bard G2 IVC filter was implanted in Ms. Booker on June 21, 2007.

In June 2014, Ms. Booker went to the Gwinnett Medical Center in Lawrenceville, Georgia for abdominal pain. Scans revealed that the filter had migrated caudally and tilted. The G2 filter had also fractured with three legs detached from the filter; one of

which migrated to her heart. Surgery was scheduled to remove the filter and fragments approximately a month later.

Ms. Booker underwent surgery on July 23, 2014 in a first attempt to remove the filter and fragments. In that surgery, the filter and one fractured strut were retrieved. A second procedure was performed on July 28, 2014 to retrieve the filter fragment from Ms. Booker's heart. At the same time, Ms. Booker had a procedure to repair a tear in her tricuspid value caused by the filter. A fractured strut remains embedded in Ms. Booker's IVC, and doctors have not been able to retrieve it.

Plaintiffs submit that Ms. Booker's case is an appropriate bellwether case as it presents the parties and the Court the opportunity to address signature complications resulting from Bard's highest-selling device, the G2. As noted above, G2 is the most dominant filing in this MDL and has the highest rate of incident reporting (51%) of Bard's IVC filters in the MAUDE database. It is also the device that is the most prevalent for filing in this MDL (41 percent overall and 61 percent of the Recovery/G2/Eclipse cases). Ms. Booker's complications are also consistent with the signature problems with the G2: caudal migration and fracture. Unfortunately, the Plaintiff Profile Forms only capture migrations to the heart (cranial), but the medical literature and the MAUDE database make clear that the G2 migrates caudally and does so at a relatively high rate; Bard's own Everest study confirms the high caudal migration rate for this device. Thus, Plaintiffs' expectation (and experience) is that there are a substantial number of G2 caudal migration cases in this MDL. Like many cases in this MDL, Ms. Booker experienced a filter fracture (249/954 cases, 26.1%), and like many others she had a perforation (325/954 cases, 34.1%). But, primarily, Ms. Booker's case is one relating to caudal migration and the resulting fracture of her G2 IVC filter. In that regard, she presents an opportunity for the parties to litigate the issues of liability and damages associated with those failures.

Ms. Booker is also of an age at which she is neither too old nor too young to represent the range of ages in this MDL. She also has retained her explanted filter, on which Bard has now had the opportunity to conduct non-destructive testing. And, because

of the device's failures and her complications as a result, her case will give both sides the opportunity to explore their best arguments relating to those issues.

C. Brent Dewitt – G2

Brent Dewitt is 45 years old and resides in New York. He is married and owns a construction and renovation company. In 2009, Mr. Dewitt was hit by a drunk driver and airlifted to Westchester Medical Center in New York with open femur and tibia/fibular fractures, hip dislocation, and splenic laceration. Given that he could not be anticoagulated and would be in a prolonged bedridden status, a Bard G2 filter was placed temporarily on September 5, 2009 by Romeo Mateo, M.D.

On December 15, 2009, Mr. Dewitt returned for removal of the filter by the same doctor, Dr. Mateo, as the filter was no longer needed. By this time, the filter had tilted and three struts were perforating through the vena cava. Despite several attempts and maneuvers, the filter could not be removed and was left in place, with the understanding that it would now be permanent.

In February 2016, Mr. Dewitt's blood pressure was noted to be high. An x-ray on March 9, 2016 disclosed that the filter had fractured and one strut had migrated to the right ventricle of the heart, while a second strut was incorporated into the vena cava wall. Mr. Dewitt was referred to Frank Lynch, M.D. at Penn State Hershey Medical Center, who attempted retrieval of the filter and fractured struts through a percutaneous approach on June 16, 2016. The fractured strut that was retained in the vena cava was removed, but detailed angiography of the filter apex showed significant perforation of the filter cap, arms, and legs, so Dr. Lynch felt that retrieval carried a high risk of caval injury and elected not to proceed. He attempted to remove the strut in the right ventricle, but it was fully embedded and could not be captured.

On December 27, 2016, Mr. Dewitt underwent a routine follow-up scan and it was discovered that the fractured strut had migrated from the heart to the right upper lobe of the lung. This strut was percutaneously removed in a second attempt by Dr. Lynch on February 21, 2017 at Penn State Hershey Medical Center. Mr. Dewitt has been advised

that the filter can only be removed through an open abdominal procedure, which is scheduled to take place in May 2017.

Plaintiffs propose Mr. Dewitt's case as a bellwether because it is representative of the numerous G2 cases filed and to be filed in this MDL. Again, G2s represent the majority of Bard's adverse events on MAUDE (51%) and are the largest device class of cases in this MDL. As with many G2 cases, Mr. Dewitt's filter suffered a fracture (like 26.1% of MDL cases and up to 38 percent of cases at five year as reported in medical literature) and the filter perforated his IVC (like 34.1% of MDL cases and 18-44% of cases reported in medical literature). Similarly, the filter's tilt (33.2% of MDL cases; up to 18% in medical literature) and embedment (32.1% in the MDL) are signature complications in this MDL. The Dewitt case, thus, presents several signature complications of the G2, including particularly the effects of caudal migration and perforation as they potentially lead to other complications, such as filter fracture.

D. Joseph Mixson – G2

Joseph Mixson is 30 years old and resides in Florida. He is married and expecting his first child this year. He is a permanently disabled veteran and currently works on a cattle ranch. In 2007, at 21 years old, Mr. Mixson was the victim of an IED explosion while deployed in Iraq as a soldier in the U.S. Army. He lost his legs and sustained a complex trauma to his elbow and an open skull fracture. He was transported to Brooke Army Medical Center in San Antonio, Texas, where he underwent multiple surgeries and subsequently developed right external iliac DVT and bilateral PE. A temporary Bard G2 filter was placed by Anthony Goei, M.D. on September 18, 2007.

Following several months of physical therapy and rehabilitation, Dr. Goei attempted to retrieve the filter on May 28, 2008 through a jugular approach. The device could not be removed as planned, as the cone and at least 3-4 legs had protruded outside the caval wall. It had also caudally migrated from the L1 to L2 disk space and had tilted. A repeat scan one year later showed that the filter struts were projecting further into the

vena cava and close to the aorta. By 2013, the filter struts were perforating the aorta and duodenum.

Mr. Mixson's filter remains implanted in a tilted, perforating position and he must now undergo annual imaging scans to monitor the device. He has consulted with three vascular surgeons, all of whom have advised that the filter cannot be retrieved through an endovascular approach and surgical removal is not recommended, as the risks of retrieving such a filter are considerable and he would also require replacement of his inferior vena cava. The filter will remain implanted permanently unless it becomes further compromised and removal becomes absolutely necessary.

Mr. Mixson's case is appropriate for inclusion in Bellwether Group 1 because it is representative of the many cases that involve the signature complications of the G2. Mr. Mixson's filter migrated caudally; again, although the PPFs do not capture caudal migrations, the medical literature and Bard's own Everest study on the retrievability demonstrate that this is a common complication of the G2. Mr. Mixson's device has tilted (like approximately one third of the filters in this MDL) and perforated his IVC (like 34.1% of the cases in this MDL). Thus, his case presents signature complications and failures of the G2 filter that are the subject of numerous cases in this MDL.

E. Justin Peterson – Eclipse

Mr. Peterson is 34 years old and resides in Portland, Oregon. He has been married for four years and has a two-and-a-half-year-old daughter. He is employed as an Assistant Manager in the produce department of local store. In 2010, Mr. Peterson was living in Pennsylvania and suffered a right fibular and femur fracture in an accident at work. Approximately three week after his injury and resultant immobility, he developed recurrent DVTs. The decision was made to place an IVC filter to protect against a possible PE. On June 26, 2010, a Bard Eclipse IVC filter was implanted at Pinnacle Health Harrisburg Hospital in Harrisburg, Pennsylvania. According to the deposition testimony of Jay Goodman, M.D., the physician who implanted the filter, the filter was deployed in good position below the renal veins, along the axis of the vena cava.

On February 13, 2015, Mr. Peterson was admitted to the hospital in Portland, Oregon for rectal bleeding, hypotension, and tachycardia. A CT scan performed the next day demonstrated that two of the struts from his IVC filter had perforated the caval wall and penetrated his duodenum. Other struts were perforating into the psoas muscle. On February 17, 2015, Mr. Peterson underwent an open abdominal surgical procedure to remove the filter and repair his duodenum. Mr. Peterson subsequently developed a hematoma and an incisional hernia that required surgical repair.

Perforation of the struts of a Bard IVC is filter is a common failure mode – it appears in more than 34 percent of cases in this MDL and up to 44% of cases in the medical literature. Such perforations can result in injury to other organs. As such, Mr. Peterson's case is representative of large number of plaintiffs who have suffered a perforation from the IVC filter as well as those who have had significant injuries develop from perforation. As a bellwether case, the jury would have opportunity to focus on the evidence regarding the Eclipse filter's design, effectiveness, and performance (which with regard to perforation are the same as the G2). In the event liability is established, his damages are of the same nature as most all plaintiffs, pain and suffering, mental anguish, physical disability, and past and future medical expenses. His case would provide a very strong model of the type of verdict that is likely to result in a significant number of MDL cases that involve the need for an open surgical procedure for retrieval of the filter.

VI. Defendants' Proposed Cases

As distinct from Plaintiffs' proposed cases, Defendants' proposed cases skew both towards the Eclipse (Defendants propose three Eclipse cases despite the fact that Bard sold less of that device than of any of its IVC filters) and single (and redundant) failures and complications. Trying the slate of cases that Bard proposes will do little to provide the parties the opportunity to present their best arguments or to test their theories and defenses at trial. And, they will provide the Court and the parties with little, if any, reliable information that will be useful to settlement of the other cases in this MDL.

The following chart summarizes Defendants' proposed cases (Plaintiffs provide a more detailed explanation of each case below):

Name	Device	Retrieval attempt(s)	Failure Mode(s)	Residual(s)
Hyde	G2	Successful complex retrieval of fractured strut from right ventricle and filter from IVC	Fracture, Migration (strut)	None
Jones	Eclipse	Successful percutaneous retrieval of filter	Fracture	Strut in right pulmonary artery
Nelson	Eclipse	Successful percutaneous retrieval of filter	Fracture	Strut embedded in IVC
Kruse	G2	Unsuccessful percutaneous retrieval attempt	Migration (Filter), Irretrievable	Filter embedded in IVC
King	G2	Unsuccessful percutaneous retrieval attempt	Irretrievable	Filter is in IVC

A. Lisa Hyde – G2

Lisa Hyde is a 52 year old married mother of three who resides in California. In February 2011, Ms. Hyde reported to the emergency room at Franklin Hospital in Wisconsin with complaints of thigh pain and shortness of breath. She was diagnosed with a non-occlusive thrombus and pulmonary embolus, and had a Bard G2 filter implanted. In May 2014, Ms. Hyde was having lower back pain and abdominal pain; she underwent an abdominal CT which revealed that her filter had fractured and a strut had broken off and migrated to her right ventricle. She suffered chest pains thereafter but the filter strut did not perforate the ventricle. In late August 2014, Ms. Hyde underwent a complex percutaneous retrieval of the filter at Stanford Medical Center in California during which both the filter and the fractured strut were retrieved and removed without incident.

Plaintiffs believe that Ms. Hyde would be an appropriate bellwether case if the deposition actions of her treating doctors' attorneys can be cured. In particular, during the depositions of Ms. Hyde's treating doctors, the lawyers for those treating doctors interposed inappropriate objections and instructed their doctors not to answer questions on

grounds not permitted in the Rules of Civil Procedure. *See* addendum of examples at Ex. 8. As a result, the doctor depositions in the Hyde case are not appropriate for use at trial.

Plaintiffs proposed to Defendants to stipulate to the inclusion of the Hyde case in Bellwether Group 1 if Defendants would agree that Plaintiffs can take trial depositions of the treating doctors either with a special master present or this Court attending by phone. Plaintiffs simply desire that the treating doctor testimony be presented as it would at trial, and not interrupted by counsel who have no involvement in this case. If this case were to proceed to trial in Ms. Hyde's home venue (where she could compel the attendance of the witnesses at trial), she would have that opportunity. Having waived *Lexicon* to permit this case to proceed as a bellwether, Ms. Hyde should not be prejudiced by that waiver, and Plaintiffs believe this is a fair resolution.

Defendants rejected this proposal. Nonetheless, Plaintiffs would stipulate to the inclusion of Ms. Hyde's case in the bellwether case pool if this Court were to permit short trial depositions of her treating doctors with a special master present (for which Plaintiffs will pay) or the Court's attendance by phone to ensure that Ms. Hyde has true trial testimony from those doctors unobstructed by counsel not involved in the case.

B. Doris Jones – Eclipse

Doris is a 51 year-old married woman and resident of Savannah, Georgia. Ms. Jones had an Eclipse IVC filter implanted in her IVC in August 2010 during an extended hospitalization due to gastrointestinal issues, including gastrointestinal surgery. Following surgery and during her hospital stay, Ms. Jones developed a DVT, which was treated by the IVC filter. At the time of placement, her physician indicated that the filter was likely to remain permanent. In 2015, Ms. Jones reported to the hospital for unrelated issues. A chest X-ray and subsequent CT demonstrated that an arm of the filter had broken off and migrated through her heart to her right pulmonary artery. The filter was removed percutaneously, but the doctors determined that the broken arm was located in a dangerous area and not suitable for retrieval. The broken filter arm remains in Ms. Jones's pulmonary artery.

Case-specific discovery did not reveal anything that makes this case particularly suitable as a bellwether trial. Ms. Jones suffered a signature injury for Bard's IVC filters – a fracture. That being said, there is nothing about Ms. Jones's case that makes it a better option for a bellwether trial than the fractures presented in other cases, such as the Dewitt and Booker cases (both of whom had G2 filters).[9]

Indeed, as noted above, filter fracture is a common failure mode for Bard IVC filters. And, many patients have fractured struts that remain in their bodies and require medical monitoring to determine the strut status. In that sense, Ms. Jones is representative of the significant number of plaintiffs who have experienced a filter failure and live with the knowledge that they have a piece of metal in their body that could move and cause further injury or death at any time. However, this is also true of Mr. Dewitt, Ms. Hyde, and Mr. Nelson – all of whom had fractures and retained the broken struts in their bodies.

Additionally, for purposes of trying fracture cases that will provide information useful across the MDL, Eclipse cases are the least effective bellwethers. Although BPV's Vice President of Research & Development testified that there is no evidence in Bard's testing that the electropolishing improved fracture resistance, migration resistance, or corrosion resistance, *see* Ex. 7, Bard marketed the device as being more fracture resistant than is predicate devices (the G2 and Recovery) based on the electopolishing. Thus, an Eclipse fracture case raises issues specific to Eclipse fractures and not necessarily fractures in the prior devices. And, according to the PPFs, there are only 33 Eclipse fracture cases among the 954 cases for which the parties have PPFs (as compared to, for example, 126 G2 fractures).

Furthermore, given that both sides have agreed on the Mulkey case as a bellwether trial for Eclipse filters, the inclusion of the Jones case would cause the Eclipse to be significantly overrepresented in the bellwether pool. Indeed, Ms. Jones's case is one of three Eclipse cases proposed by Defendants – half their proposed bellwether pool. That

[9] While Ms. Jones's Eclipse was electropolished, the arm fracture occurred where the arm met the device cap, an angle fracture that electropolishing (which smoothed the surface of the device) was not designed to address or to reduce the incidence.

ratio (50 percent) both far exceeds the ratio of Eclipse cases in the first 954 PPFs (less than a third of the Recovery-G2-Eclipse PPF cases) and is well in excess of Bard's relative sales figures for the device (which put Eclipse at approximately 1/8 the sales of G2 and only 2/3 the sales of Recovery).

Because of its limited application (only 32 Eclipse fracture cases) and its relative simplicity (single failure), Ms. Jones case will provide both the parties and the Court with less useful information as to the parties' best arguments and the testing of theories and defenses at trial as compared to the Dewitt case, for example.

Finally, in Jones and Nelson, Bard presents two very similar cases – both are Eclipse fracture cases in which the fractured filter piece remains in the patient. Although the location of the fractured strut is different, Bard cannot present a meaningful argument for trying two cases that are so similar.

C. Nelson – Eclipse

Randy Nelson is 53 years old and lives in Sioux Falls, South Dakota. He has been married for 31 years and has two children. He is employed as a direct support professional representative for persons with disabilities. In June 2013, he suffered head and leg injuries following a scooter accident. He subsequently developed a DVT and, on June 20, 2013, had a Bard Eclipse filter implanted at USD Medical Center in Sioux Falls, South Dakota.

On October 24, 2013, after his DVT was no longer considered a threat, his filter was removed percutaneously. During the retrieval at USD, doctors determined that the filter had tilted and one leg had fractured (pre-retrieval). They attempted to remove the strut, but it was firmly embedded in the IVC wall, could not be retrieved during the procedure, and remains embedded. He has had three follow up scans to determine the strut status, and the strut continues to be in his IVC in the area of his mid-upper abdomen.

Like Ms. Jones's case, case-specific discovery did not reveal anything that would make Mr. Nelson's case particularly suitable as a bellwether trial. Nor is there anything about Mr. Nelson's case that makes it a better option for a bellwether trial than the

fractures presented by the Dewitt and Booker cases (which are G2 cases). And, because, like Ms. Jones, Mr. Mulkey suffered a fractured Eclipse and retains the fractured strut in his body, his case suffers from the same problems identified above as to Ms. Jones's case.

And, as mentioned above, selection of both Jones and Nelson – as Defendants suggest – would amplify those problems by putting two substantially similar cases in the bellwether pool for a device (Eclipse) that represents a true minority of Bard's filter sales.

D. Kruse – G2

Carol Kruse is a 70 year old married registered nurse and mother who resides in Nebraska. In July 2009, she had a G2 filter implanted in Nebraska prior to a total knee arthroplasty procedure. In April 2011, she had an unsuccessful percutaneous retrieval attempt in Nebraska after her filter was noted to have migrated. The filter remains implanted and out of position. Ms. Kruse has been diagnosed with Leukemia, though Plaintiffs are not aware of its status.

Ms. Kruse's case originates from Nebraska where her device was implanted and where she lives. Nebraska does not allow punitive damages. Although the issue of which substantive laws will be applied to the bellwether trials has not yet been addressed by the court, plaintiffs are concerned that if Nebraska laws were applied, then the inclusion of this case would yield little value as a bellwether. Plaintiffs firmly believe that the Defendants' conduct will result in a significant punitive damage award and selecting a bellwether trial that potentially eliminates this from deliberation will be a waste of both resources and time.[10]

E. King – G2

Michael King is a 70-year old retired welder and father of three; he is a resident of Illinois. In August 2008, Mr. King was involved in the crash of an ultralight aircraft and

[10] The importance of punitive damages in these cases is demonstrated by the recent verdicts in the *In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant Products Liability Litigation*, MDL No 2244 (N.D. Tex.), in which the jury awarded one billion dollars in punitive damages against the defendants. The impact of large punitive damage awards in creating incentives to settle and the negotiation of settlement ranges is obvious.

suffered significant injuries, resulting in him falling into a coma. While in a coma, Mr. King developed DVT and was implanted with a G2 IVC filter.

In February 2016, Mr. King saw Dr. James Burks about the potential removal of his G2 filter. A preliminary scan revealed that the filter was occluded with clotting and, thus, retrieval was not an option at that time. On March 8, 2016, Dr. Burks attempted to retrieve Mr. King's G2 filter. At deposition, Dr. Burks testified that the filter appeared to be appropriately placed in the IVC at the time of the attempt. He further testified that images were taken of the filter both pre- and post-retrieval attempt, but those images were inadvertently destroyed by a member of his staff. Dr. Burks testified that he used a Cook IVC filter retrieval system to attempt to retrieve Mr. King's filter and that he attempted to use that device to snare one of the filter legs in order to pull the filter out. He was unable to cause the device to detach from the IVC. Mr. King's filter remains implanted.

At his deposition, Dr. Burks admitted that the G2 Instructions for Use required the use of the Bard Recovery Cone for retrieval of the G2 filter and admitted that he did not use that device. Candidly, Dr. Burks's use of the Cook device raises significant problems for the viability of Mr. King's case. The Bard Recovery Cone retrieval device operates by covering the filter from the top and effectively collapsing it into the cone – the way one would collapse an umbrella. Dr. Burks's retrieval method apparently was simply to tug at the filter to determine if it would come free. Based on his testimony and records, the filter remained intact and centered in the IVC without significant tilt or other complication after his failed retrieval attempt.

Plaintiffs submit that Mr. King's case is not representative of other cases in this MDL[11] and trying the case will not provide information helpful to the resolution of other cases. Based on Dr. Burks's testimony, Plaintiffs believe that his actions and testimony would be the centerpiece of any trial – both his use of the incorrect device in the retrieval attempt and his failure to maintain the images of the device before and after his retrieval

[11] Plaintiffs note that Mr. King's case was one of Defendants' four designated cases for automatic inclusion in Discovery Group 1.

attempt. On the first issue, Plaintiffs believe Defendants will raise significant questions regarding whether the filter is, in fact, irretrievable; and, based on Dr. Burks's testimony (particularly that the filter remains well centered and he used the wrong device in his attempt to retrieve it), Plaintiffs believe that a jury could reasonably conclude that the device has not failed at all and remains retrievable even now. On the second issue, Defendants cross examined Dr. Burks regarding the loss of the pre- and post-retrieval images, and he admitted that he had lost the only evidence that could establish that his actions in attempting to retrieve the filter (particularly using the wrong retrieval device and tugging at the filter) had not adversely affected it. Consequently, if there are future complications, Bard has made a strong argument to blame Dr. Burks for those results.

The circumstances of this case are simply too unique for it to be beneficial as a bellwether trial. There are not other cases that have these facts. And, trial of this case will be more about Dr. Burks than the G2 filter or Mr. King's injuries.

VII. Composition of Bellwether Group 1

Based on Bard's sales figures for the relevant devices, MAUDE complication reporting, and the case composition of the MDL according to the 954 PPFs completed to date, Plaintiffs suggest that Bellwether Group 1 should be comprised of one Recovery case, four G2 cases, and one Eclipse case. They further suggest there should be multi-complications cases that include migration (both cranial and caudal), perforations, fractures, and embedments. This will ensure a more representative sampling of the MDL cases and will likely provide more reliable information about other cases.

A. Recovery – Tinlin, the sole Recovery case

In this first phase of bellwethers, there should be at least one Recovery case. That case should be Tinlin, which is the Court's only real option. The Kaiser case is the only other Recovery case in Discovery Group 1, and, despite of it being one of their automatic inclusions in Discovery Group 1, Defendants have recognized that case is not an appropriate bellwether case.

B. The G2/G2 equivalent cases – Booker, Dewitt, Mixson, and Peterson

This Court should choose four G2 cases (or cases that are equivalent to a G2). Plaintiffs recommend Booker (caudal migration of filter, perforation, and fracture), Dewitt (fracture, filter perforation and embedment, fragment migration and retrieval), Mixson (perforation, slight filter migration, and filter embedment), and Peterson (perforation and complete retrieval). Although Peterson is an Eclipse, it does not present Eclipse-specific issues (the issues relating to electropolishing and its effect [if any] on fracture rates). In the event the Court agrees with Plaintiffs' suggestion regarding the inclusion of the Hyde case (fracture and migration of strut; complete removal of device and fractured strut), Plaintiffs would recommend it be in lieu of the Peterson case. These cases are representative of the failure modes at issue for these devices and provide a variety of failure modes and injuries to provide a good representative of the different issues and argument that apply across the MDL with respect to the numerous G2 cases. The other G2 options (Kruse and King) are far less appropriate for the reasons discussed above.

C. Eclipse– Mulkey

As the parties have agreed on Mulkey, the Court should chose it as the sole Eclipse case. Mulkey was a defense selection at each of the prior stages, and Plaintiffs agree that it would be an appropriate case to include in the bellwether pool as representative of Eclipse cases.

Defendants, however, propose to overload the bellwether pool with three Eclipse cases. For reasons discussed above with respect to the Jones and Nelson cases, their inclusion would skew the bellwether process to a relatively low selling device and focus largely on issues specific to that device.

Moreover, the inclusion of an additional Eclipse case would have to come at the expense of a G2 case (the device that dominates both case filings and Bard's sales numbers). If the Court is inclined to include a second Eclipse, Plaintiffs submit it should be the Peterson case as it presents a different failure mode (perforation) than the other

Eclipse cases (Jones and Nelson are both fracture) and would provide greater information to the parties as its facts have potential application to other non-Eclipse cases in the MDL.

VIII. Conclusion

Accordingly, Plaintiffs recommend that the Court select the following cases for Bellwether Group 1:

- Debra Tinlin, case no. 16-CV-00263 (Recovery filter);
- Sherr Unna Booker, case no. 16-CV-00474 (G2 filter);
- Brent Dewitt, case no. 16-CV-00474 (G2 filter);
- Joseph Mixson, case no. 16-CV-00268 (G2 filter);
- Justin Peterson, case no. 16-CV-00774 (Eclipse filter);
- Deborah Mulkey, case no. 16-CV-00853 (Eclipse filter)

If the Court agrees with Plaintiffs regarding the case of Lisa Hyde, case no. 16-CV-00893 (G2 filter), Plaintiffs would recommend that case in place of Peterson above.

RESPECTFULLY SUBMITTED this 24th day of April 2017.

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CERTIFICATE OF SERVICE

I hereby certify that on this 24th day of April, 2017, I e-mailed Plaintiffs' Submission for Bellwether Group 1 to Judge Campbell's chambers per Case Management Orders 11 and 18 and sent copy by e-mail to defense counsel.

/s/ Deborah Yanazzo

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